UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA EX REL. [UNDER SEAL]	)	C.A. No. 04-2511
	)	(Johnson, J.)
Plaintiffs,	)	(Levy, M.J.)
v.	)	
	)	SECOND AMENDED COMPLAINT
[UNDER SEAL]	)	
Defendants	)	
	)	

FILED IN CAMERA AND UNDER SEAL

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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, et al., EX REL. THOMAS CANTOR, Plaintiffs, v. AMGEN, INC.; AMERISOURCE BERGEN CORPORATION; INTERNATIONAL NEPHROLOGY NETWORK; WATSON PHARMACEUTICALS, INC.; and SIGMA-TAU PHARMACEUTICALS, INC.) Defendants.	C.A. No. 04-2511 (Johnson, J.) (Levy, M. J.) **SECOND AMENDED COMPLAINT** FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. §3729 et seq.]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt Code §12650 et seq.]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C. §1201]; FLORIDA) FALSE CLAIMS ACT [Fla. Stat. Ann. §68.081 et seq.]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. §661-21 et seq.]; ILLINOIS WHISTLE BLOWER REWARD AND PROTECTION ACT [740 Ill. Comp. Stat. §175 et seq.]; MASSACHUSETTS FALSE CLAIMS LAW [Mass Gen Laws ch.12 §5 et seq]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. §357.010 et seq.]; NEW MEXICO MEDICAID FALSE CLAIMS REWARD AND PROTECTION ACT [740 Ill. Comp. Stat. §175 et seq.]; MASSACHUSETTS FALSE CLAIMS

LAW [Mass Gen Laws ch.12 §5 et seq]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. §357.010 et seq.]; NEW MEXICO MEDICAID FALSE CLAIMS ACT [N.M. Stat. Ann. §27-2F-1 et seq.]; NEW MEXICO FRAUD AGAINST TAXPAYERS ACT [N.M. Stat. Ann. §41-14-1 et seq.]; TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. §71-5-181 et seq.]; TEXAS MEDICAID FRAUD PREVENTION LAW [Tex. Hum. Res. Code Ann. §36.001 et seq.]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Code Ann §8.01-216.1 et seq.]; DISTRICT OF COLUMBIA FALSE CLAIMS ACT [D.C. Code Ann. § 2-308.14 et seq.]; GEORGIA FALSE MEDICAID CLAIMS ACT [O.C.G.A. §§ 49-4-168 et seq.]; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT [I.C. §5-11-5.5]; LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW [La. Rev. Stat. §437 et. seq]; MICHIGAN MEDICAID FALSE CLAIMS ACT [MCL 400.601-400.613]; NEW HAMPSHIRE FALSE CLAIMS ACT [N.H. Rev. Stat. Ann. §167:61 et seq.]NEW YORK FALSE CLAIMS ACT [N.Y. State Fin. §§ 187 et seq.]; OKLAHOMA MEDICAID FALSE CLAIMS ACT [2007 OK. ALS 137]; CONNECTICUT FALSE CLAIMS ACT, [Conn. Publ. L 09-05]; NEW JERSEY FALSE CLAIMS ACT [N.J. Stat. § 2A:32C-1 et seq.]; RHODE ISLAND FALSE CLAIMS ACT [R.I. Gen. Laws §9-1.1-1 et seq.]; and WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT [Wis. Stat §20.931 et seq.].

Plaintiff-Relator, Thomas Cantor, through his attorneys Phillips & Cohen LLP and Getnick & Getnick, on behalf of the United States, the State of California, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Massachusetts, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Virginia, the State of Wisconsin, and the District of Columbia (collectively "the States"), for his Complaint against defendants Amgen, Inc. ("Amgen"), AmerisourceBergen Corporation ("AmerisourceBergen"), International Nephrology Network ("INN"), Watson Pharmaceuticals, Inc. ("Watson"), and Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") alleges as follows.

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the States arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by defendants and/or their agents, employees

and co-conspirators, in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 et seq., as amended ("the FCA" or "the Act"), and the false claims acts of the States as set forth below.

2. Defendants' acts also constitute violations of the California False Claims Act, Cal. Govt Code §12650 et seq.; the Connecticut False Claims Act, Conn. Publ. Law 09-05; the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. §68.081 et seq.; the Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1-8; the Indiana False Claims and Whistleblower Protection Act [I.C. §5-11-5.5]; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §437 et seq.; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 et seq.; the Michigan Medicaid False Claims Act, MCL 400.601-400.613; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 et seq.; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167:61 et seq.; the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-14-1 et seq.; the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §44-9-1 et seq.; the New York False Claims Act, N.Y. State Fin. §§ 187 et seq.; the Oklahoma Medicaid False Claims Act, 2007 OK. ALS 137; the Rhode Island False Claims Act, R.I. Gen. Laws §9-1.1-1 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 et seq.; the Wisconsin False Claims for Medical Assistance Act, Wis. Stat §20.931 et seq.; and the District of Columbia False Claims Act, D.C. Code Ann. §§ 2-308.14 et seq.

3. Residents of the United States spend approximately two hundred billion dollars annually on prescription drugs. Pharmaceutical manufacturers fiercely compete with one another

for sales in this lucrative market. A large share of these sales are paid for in whole or in part by health insurance programs funded by the federal and state governments.

4. The federal and state governments have enacted strict limitations on pharmaceutical manufacturers' marketing and promotional practices. These laws are intended to ensure that medical providers make recommendations as to prescription drug usage based upon informed, impartial medical judgment. As alleged below, defendants have circumvented a number of these laws by promoting prescription drugs (i) through illegal kickback schemes, and (ii) through off-label promotion. As a direct result of defendants' unlawful practices, the federal and state treasuries have been damaged in a substantial amount.

5. The FCA was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act. Congress enacted the 1986 amendments to enhance and modernize the federal government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of government frauds to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the government's behalf.

6. The Act provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government; knowingly makes, uses, or causes to be made or used false records and statements to induce the United States to pay or approve false and fraudulent claims; conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; or knowingly conceals, avoids, or decreases an obligation to pay or transmit money or property to the federal government, is liable for a civil penalty of up to

$11,000 for each such claim, plus three times the amount of the damages sustained by the federal government.

7. The Act allows any person having information about false or fraudulent claims to bring an action for himself and the government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendants during that time). Based on these provisions, and the provisions of the comparable state law statutes, qui tam plaintiff and relator Thomas Cantor seeks through this action to recover treble damages and civil penalties arising from the following categories of fraudulent conduct:

a. Defendant Amgen illegally promotes its drugs, including the newly-marketed drug Sensipar, by using aggressive marketing practices that are prohibited by Congress and the Food and Drug Administration. As a result, claims for the payment of Amgen drugs induced by such illegal practices are rendered false or fraudulent.

b. Defendants INN and Amgen illegally promote Amgen's drugs, including Aranesp, by "marketing the spread" between the drug's artificially high AWP price (which is the basis for federal and state reimbursements), and the deeply discounted actual cost of the drug to nephrologists and other providers. As a result, claims for the payment of Amgen drugs induced by this illegal kickback practice are rendered false or fraudulent.

c. Defendants INN and Watson illegally promote Watson's drug Ferrlecit by "marketing the spread" to providers in violation of anti-kickback laws, and by promoting the drug for off-label uses in violation of FDA requirements. As a result, claims for the payment of Ferrlecit induced by these illegal practices are rendered false or fraudulent. INN also promotes the reimbursement advantages to providers of administering Ferrlecit by one-hour intravenous infusion

rather than by a faster intravenous push injection. This promotional practice induces providers to bill government health care programs for medically unnecessary one hour infusion services.

d. Defendant Sigma-Tau illegally promotes its drug Carnitor by "marketing the spread" to providers, in violation of anti-kickback laws. As a result, claims for the payment of Carnitor induced by this illegal kickback practice are rendered false or fraudulent.

II. PARTIES

8. Plaintiff-Relator Thomas Cantor ("Cantor" or "Plaintiff") is a resident of El Cajon, California. He is the founder, President and CEO of Scantibodies Clinical Laboratory, Inc. and Scantibodies Laboratory, Inc. (collectively "Scantibodies"). Scantibodies is a California corporation and is located in Santee, California. Scantibodies produces diagnostic test antibodies and diagnostic test kits. Scantibodies produces kits to test levels of parathyroid hormone ("PTH") hormone and performs PTH testing in-house for dialysis patients. Cantor has decades of first-hand experience working in the medical field, and has spent thousands of hours working directly with nephrologists, employees of dialysis clinics, laboratories and health care providers. Based on this experience, Cantor has developed extensive knowledge of the patient population afflicted with renal disease, of the methods of diagnosis and treatment of this condition and its related complications, and of the marketing practices of companies that sell products used in the diagnosis and treatment of this condition. The allegations in this Complaint are based upon information that Cantor discovered through his work in this field, and through his own personal efforts, observations, and investigation.

9. Defendant Amgen, Inc., is a Delaware corporation with headquarters in Thousand Oaks, California. Amgen is a global biotechnology company, with total operating revenues of $8.4 billion in 2003. Among its pharmaceutical products, Amgen manufactures (i) Epogen, an anti-

anemia drug for dialysis patients, (ii) Aranesp, a second-generation version of Epogen; and (iii) Sensipar, a treatment for secondary hyperparathyroidism.

10. Defendant International Nephrology Network is a group purchasing organization, with headquarters in Baltimore, Maryland. INN is owned by AmerisourceBergen Corporation. AmerisourceBergen is a Delaware corporation with headquarters in Chesterbrook, Pennsylvania. AmerisourceBergen is a pharmaceutical services provider. For purposes of this complaint, "INN" will refer to both International Nephrology Network and its corporate parent, AmerisourceBergen.

11. Defendant Watson Pharmaceuticals, Inc. is a Nevada corporation with headquarters in Corona, California. Watson is a pharmaceutical company that develops, manufactures, and markets pharmaceutical products. Among its pharmaceutical products, Watson manufactures the drug Ferrlecit, which is approved for treatment of iron deficiency anemia in patients undergoing chronic hemodialysis.

12. Defendant Sigma-Tau Pharmaceuticals, Inc. is a pharmaceutical company with headquarters in Gaithersburg, Maryland. Sigma Tau is a subsidiary of the Rome, Italy-based Sigma-Tau, S.p.A. Sigma Tau is primarily dedicated to the development and production of orphan drugs. Sigma-Tau manufactures the drug Carnitor, a treatment for carnitine deficiency in dialysis patients.

III. JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and 31 U.S.C. §3732. In addition, 31 U.S.C. §3732(b) specifically confers jurisdiction on this Court over the state law claims asserted in this Complaint. This Court also has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367. Moreover, the statutory bar in 31 U.S.C. §3730(e) does not apply to the facts and circumstances of this action

since there were no statutorily relevant public disclosures of the allegations or transactions upon which this Complaint was based prior to filing this action. Plaintiff Cantor had direct and independent knowledge of these allegations and transactions, and voluntarily disclosed them to the government, prior to filing this action.

14. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the defendants have minimum contacts with the United States. Moreover, one or more of the defendants can be found in, reside, or transact or have transacted business in the Eastern District of New York.

15. Venue is proper in the Eastern District of New York pursuant to 31 U.S.C. §3732(a) because one or more of the defendants can be found in and transact or have transacted business in this district. In addition, statutory violations, as alleged herein, occurred in this district.

IV. APPLICABLE LAW

A. Federal Anti-Kickback Laws Prohibit The Offering Of Financial Rewards To Induce The Purchase Of Goods Or Services Paid For By Federal Monies

16. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

17. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase

of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company that has as one of its purposes inducement of a physician to write additional prescriptions for the company's pharmaceutical products.

18. Violation of the Anti-Kickback statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7).

19. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider under the Medicare, Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, and other federal health care programs. With regard to Medicare and Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicare and Medicaid providers to agree that they will comply with all legal requirements, which include the anti-kickback provisions of the law. In a number of states, the Medicare and Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicare or Medicaid program, including compliance with Federal laws.

20. In sum, either pursuant to provider agreements, claims forms, or other appropriate manner, pharmacists and physicians who participate in a federal health care program generally must

certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

21. Any party convicted under the Anti-Kickback statute must be excluded (i.e., not allowed to bill for services rendered) from federal health care programs for a term of at least five years. 42 U.S.C. §1320a-7(a)(1). Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agency(ies) to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. §1320a-7(b).

22. The enactment of these various provisions and amendments demonstrates Congress's commitment to the fundamental principle that federal health care programs will not tolerate the payment of kickbacks. Thus, compliance with the Anti-Kickback statute is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicare, Medicaid and other federal health care programs.

23. Similarly, compliance with the federal anti-kickback statute and comparable state anti-kickback statutes is a prerequisite to a provider's right to receive or retain reimbursement payments from state-funded health care programs.

1. Pharmaceutical Manufacturers Are Prohibited From Offering Financial Inducements To Providers By "Marketing The Spread" Between Deeply Discounted Products And Health Care Program Reimbursements

24. In May 2003, the Inspector General of HHS released formal guidance to pharmaceutical manufacturers, identifying several marketing practices that constitute "kickbacks and other illegal remuneration" infecting federal health care programs. OIG Compliance Program

Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003). The 2003 Guidance cautions manufacturers against, among other things, engaging in the suspect practice of "marketing the spread."

25. The "spread" refers to the difference in value between what a provider pays for a drug and the reimbursement that the provider receives (usually from government or private health insurance) for a drug that is administered to the beneficiary. The greater the difference between provider cost and program reimbursement, the greater the "spread" - and the greater the provider profit.

26. Under the Medicare program, and other federal and state health insurance programs, prescription drug reimbursement amounts generally use the Average Wholesale Price ("AWP") as a "benchmark" price. During the time period relevant to this Complaint, Medicare Part B generally reimbursed covered drugs at 95 percent of their AWP.

27. The AWP for a prescription drug is a self-reported amount - i.e., it is not independently or objectively determined. Rather, manufacturers provide AWP data to publications such as First Data Bank, which then publish the data without further scrutiny.

28. Pharmaceutical manufacturers engage in unlawful kickbacks when they maintain an artificially high AWP for a drug - thereby increasing federal and state reimbursement amounts - and then market the drug at deeply discounted prices to providers. The Anti-Kickback Act is triggered when the manufacturer induces drug purchases by deeply discounting a drug off an artificially high AWP.

29. By "marketing the spread" between the actual, discounted price and the higher, federal reimbursement amount (95 percent of the artificially high AWP), a drug manufacturer is offering purchasers an illegal inducement to purchase the product.

30. The OIG's 2003 Guidance cautions manufacturers against "marketing the spread." The 2003 Guidance states that "[t]o the extent that a manufacturer controls the 'spread,' it controls its customers profit." It further observes that "[t]he conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute." 68 Fed. Reg. at 23736-37.

2. Pharmaceutical Manufacturers Are Prohibited From Giving A Price Concession On One Drug In Order To Induce The Purchase Of A Different Drug

31. The anti-kickback statute prohibits a manufacturer from offering or paying "*any* remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly" to induce the purchase of goods or services payable by the federal government. 42 U.S.C. § 1320a-7b(b)(2) (emphasis added). Illegal remuneration under the statute includes offering rebates or other price concessions on one drug in order to induce the purchase of a different drug that is reimbursable by the federal government. 56 Fed. Reg. 35952 (July 29, 1991) (Office of Inspector General, HHS, Issuance of Final Rules Implementing The Anti-Kickback Act).

32. When HHS issued regulations in 1991 implementing the anti-kickback statute, it specifically addressed the practice of a seller offering discounts or rebates on one drug in order to induce the purchase of another drug. In comments accompanying the final regulations, HHS made clear that "the practice of a seller giving away, or reducing the price of, one good in connection with the purchase of a different good" is prohibited by the anti-kickback statute. See id. at 35978. HHS also observed that not only does this practice implicate the anti-kickback statute, it distorts the accuracy of the manufacturer's pricing data submitted to the Government, since "bundled pricing arrangements," where the sale of one drug is linked to a discount or rebate offered on another drug, make "it difficult to determine the true acquisition cost" of the drugs. Id.

B. FDA Prohibition On The Promotion Of Off-Label Uses

33. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355(a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

34. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

35. The indications and dosages approved by the FDA are set forth in the drug's labeling, the content of which must also be reviewed and approved by the FDA. 21 U.S.C. §§352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

36. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses - i.e., uses not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. §360aaa(b) & ©. Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the

label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population .

37. The FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication; however, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA.

38. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

39. An off-label use of a drug can cease to be off label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. §360aaa(b) & (c).

40. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA have attempted to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and (2) manufacturer support for Continuing Medical Education ("CME") programs that focus on off-label uses.

41. With regard to the first practice - disseminating written information - the FDAMA only permits a manufacturer to disseminate information regarding off-label usage in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

42. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." Id. These factors include, among others, an examination of the relationship between the program provider and supporting company, the company's control of content and selection of presenters, whether there is a meaningful disclosure of the company's funding and role in the program, whether multiple presentations of the same program are held, whether the audience is selected by the sales and marketing department of the company, and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. Id. The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress' off-label marketing restrictions.

43. In sum, the FDCA prohibits drug companies from promoting approved drugs for unapproved uses or from making misleading claims as to the drug's safety or effectiveness. See 21 U.S.C. §§ 331, 352, 355(d). This off-label regulatory scheme protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, the FDA.

V. FACTUAL BACKGROUND

A. End Stage Renal Disease

44. Approximately 350,000 Americans suffer from End Stage Renal Disease or "ESRD" which means that their kidney function is so impaired (often as a result of high blood pressure, kidney disease or diabetes) that they must undergo dialysis to survive. The typical ESRD patient has dialysis treatments three times a week. Each treatment lasts about four hours. The only "cure" or "hope" for an ESRD patient is a kidney transplant, but there are not enough kidney donors available. ESRD patients are typically very sick and vulnerable.

45. Most ESRD patients in the United States are treated at dialysis clinics that are part of large for-profit chains. Medicare covers ESRD treatment for individuals who qualify for Social Security benefits. Medicaid provides ESRD benefits for its beneficiaries who do not qualify for Medicare ESRD coverage. Large chains derive over half their revenue from Medicare and Medicaid program reimbursements.

46. Individuals with health insurance are not eligible for Medicare coverage for the first 30 months of ESRD treatment. Thus, other federal health insurance programs including the Federal Employees Health Benefit Program (which provides health insurance for federal employees, retirees and survivors), CHAMPUS/TRICARE (providing health care insurance to

individuals and dependents affiliated with the armed forces), and CHAMPVA (providing health care coverage to families of disabled veterans) also pay for dialysis and ancillary ESRD treatments.

47. ESRD patients are critically ill and require extensive and expensive laboratory tests as well as expensive drug treatments. Several of the drugs used in these treatments are manufactured by defendants. As alleged below, defendants have knowingly induced sales of these drugs by engaging in illegal marketing and promotional practices.

B. Parathyroid Hormone

48. There are four parathyroid glands (each about the size of a pea) that are located within the thyroid gland. The parathyroid glands release parathyroid hormone ("PTH") which controls the calcium level in the blood and the rate at which bone "turns over," thus utilizing calcium. PTH controls calcium in the blood by causing the bones to increase turnover and thus release calcium into the blood stream. If the body generates too much PTH (hyperparathyroidism), the bones will release calcium into the blood at a rate that is too high, weakening the bones with the potential of leading to hypercalcemia.

49. In the otherwise healthy individuals, primary hyperparathyroidism is fairly rare, and typically results from a benign enlargement of a single parathyroid gland (adenoma). Adenoma is typically treated with surgery.

50. Secondary hyperparathyroidism, however, occurs in nearly all ESRD patients and affects all four parathyroid glands. Secondary hyperparathyroidism can lead to renal bone disease.

51. The two most common renal bone diseases are "adynamic low bone turnover disease" and "high bone turnover disease." Unless treated, very high bone turnover disease will result in the excessive release of calcium and phosphate from the bone, which can lead to ectopic

soft tissue calcification. Adynamic low bone turnover disease renders the bones unable to buffer calcium and phosphate, which also leads to ectopic soft tissue calcification. Soft tissue calcification affects the body's internal organs including the heart. Soft tissue calcification also affects blood vessels causing them to become rigid and brittle. The disease of soft tissue calcification is painful and deadly.

VI. THE DEFENDANTS' FRAUDULENT PRACTICES

A. Amgen's Illegal Financial Inducements

52. During the time period relevant to this complaint, Amgen engaged in a pattern and practice of fraudulent conduct involving the offering of illegal financial inducements to medical providers to induce them to prescribe Amgen drugs. This conduct violated the anti-kickback laws discussed in the Applicable Law section above. Amgen's marketing of the drug Sensipar is a representative example of this pattern and practice of conduct.

53. On March 8, 2004, Amgen obtained approval from the FDA to market the drug Sensipar (cinacalcet HCl) for the treatment of secondary hyperparathyroidism (secondary HPT) in patients on dialysis. Sensipar is covered by Medicaid, but is not covered by Medicare since it is a non-injectable, self-administered drug.

54. In order to successfully launch this new drug, Amgen has engaged in a variety of aggressive marketing practices, several of which overstep limits imposed by Congress and the FDA.

55. Shortly after receiving FDA approval to sell Sensipar, Amgen initiated a rebate program for its blockbuster drug Epogen that clearly furthers Amgen's marketing strategy for Sensipar.

56. Epogen is used to treat anemia in dialysis patients. Approximately 90% of all dialysis patients receive Epogen. Epogen is Amgen's bestselling drug, with gross sales in 2003 totaling $2.4 billion.

57. Amgen shares U.S. marketing rights to Epogen with Johnson & Johnson (which markets Epogen under the Johnson & Johnson trade name of Procrit). Under their marketing agreement, Amgen owns the marketing rights to Epogen in the dialysis market, and Johnson & Johnson owns marketing rights to Epogen for non-dialysis use.

58. Medicare covers Epogen, since it is an injectible drug that is used in hospitals and doctors' offices. Epogen is the largest expense in Medicare's outpatient drug budget. To hold down costs, the federal Government has set certain restrictions on the price the Government will pay for Epogen. During much of the time period relevant to this complaint, Medicare paid providers a fixed rate of $10 per 1000 units of Epogen.

59. After the FDA approved Sensipar for sale in March 2004, Amgen began a rebate program for Epogen that is designed in part to increase sales of Sensipar.

60. The Epogen rebate program is called the "Partnership Information Program" (PIP). Its first month in operation was April 2004, timed to coincide with Sensipar's first full month on the market. Under the PIP rebate program, Amgen pays rebates to dialysis clinics based on their purchases of Epogen if the clinics agree to provide Amgen on a monthly basis with patient data related to current Epogen treatment as well as potential Sensipar treatment. Specifically, the PIP rebate program offers:

a. A one half of one percent (0.5%) rebate on purchases of Epogen in exchange for "Epogen Related Patient Data," i.e., patient identifying information, hemoglobin level, and date of blood draw;

b . A one half of one percent (0.5%) rebate on purchases of Epogen in exchange for "Epogen Dose Data," i.e., patient identifying information, Epogen dose administered, and date of administration; and

c. A one percent (1.0%) rebate on purchases of Epogen in exchange for patient "Bone Metabolism Data" related to potential treatment with Sensipar. The bone metabolism data consist of patient identifying information, date of blood draw, level of PTH, calcium, phosphorous, and calcium phosphorous product. These are the precise laboratory measurements that determine, under National Kidney Foundation guidelines, whether a patient should be treated for Secondary HPT (Sensipar's approved indication).

The rebates are cumulative, and a clinic can qualify for all three rebates if it agrees to provide all of the requested data.

61. While the first two rebates listed above (0.5% each) are paid to Epogen purchasers in exchange for providing Amgen with patient information related to Epogen use and the condition it treats (anemia), the third rebate (1%) is paid to Epogen purchasers for providing Amgen with patient information related to the condition Sensipar treats (secondary HPT). The one percent rebate is paid for patient data that determines whether a diagnosis of HPT, and therefore treatment with Sensipar, is appropriate.

62. Because the three rebates are cumulative, a clinic that provides all of the requested data will receive a two percent rebate on Epogen purchases. Since sales of Epogen are estimated to be at least $2.5 billion in 2004, a two percent rebate on total sales represents *tens of millions of dollars* in rebates. For even a small dialysis clinic, the two percent rebate on Epogen purchases can amount to hundreds of thousands of dollars. Also, because the Government's reimbursement price for Epogen is fixed, the clinics pocket 100% of the rebate.

63. Plaintiff is informed and believes that one purpose of the Epogen rebate program is to funnel large sums of money to dialysis clinics with the ultimate goal of inducing them to prescribe Sensipar. This is evident from the following circumstances, among others:

a. Amgen is paying literally millions of dollars in rebates to dialysis clinics in exchange for their providing a relatively small amount of information on each dialysis patient. The rebate payments to the clinics far exceed the cost to the clinics of providing this information.

b. Even though the rebate is paid on purchases of Epogen, the largest share of the rebate is paid in exchange for patient information relevant to diagnosing HPT, for which Sensipar is an approved treatment. This provides Amgen with valuable information to market Sensipar to a targeted population.

c. The rebate program was timed to coincide with the introduction of Sensipar to the market. By paying the dialysis clinics huge sums of money in rebates at this pivotal point in time, plaintiff is informed and believes that Amgen is attempting, among other objectives, to gain the attention of the market, increase customer loyalty, and promote sales of Sensipar.

64. In addition to this rebate scheme, Amgen has offered other financial inducements to medical providers in order to promote Sensipar.

65. In a May 2003 Guidance to pharmaceutical manufacturers, the Inspector General of HHS specifically warned manufacturers that giving medical providers gratuities of more than trivial value for the purpose of inducing sales of drugs reimbursed by the federal government runs afoul of the anti-kickback statute. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).

66. In disregard of this Guidance, Amgen targets doctors with a high-volume nephrology practices and provides them with (1) free luxury trips and (2) expensive meals and gratuities, among other items, for the purpose of influencing their prescribing practices. For example:

a. In the Spring of 2004, shortly after the FDA approved Sensipar for sale, Amgen paid all expenses for approximately 100 high-prescribing nephrologists to attend a meeting concerning Sensipar at a luxurious vacation spot in Arizona. Drs. Richard Amerling, Hassan Fehmi, and William Goodman were among those attending this meeting. Following this meeting, many of those in attendance began to order Sensipar. For example, Dr. Richard Amerling prescribed Sensipar for approximately 30 of his patients following this meeting.

b. In 2003 Amgen paid for all expenses for approximately 100 nephrologists to be treated to dinner at an expensive Los Angeles hotel for a dinner meeting concerning Sensipar. Among those attending were Dr. Richard Amerling and Dr. William Goodman.

67. Plaintiff is informed and believes that the above examples are not unique, and that Amgen has paid for other trips and free events of a similar nature. Plaintiff is informed and believes that these gratuities and payments are intended to and do induce nephrologists to prescribe Sensipar, in violation of the anti-kickback statute.

68. Plaintiff is further informed and believes that Amgen's fraudulent practices described above are representative of a pattern and practice of fraudulent conduct by Amgen affecting the marketing of all of the Amgen drugs. In Plaintiff's experience, Amgen's sales and marketing practices are directed and coordinated from the company's headquarters. In Plaintiff's experience, Amgen dictates consistent practices company-wide, and Amgen's sales and marketing personnel throughout the country follow similar practices. Amgen headquarters would not have

permitted the practices described above if those practices did not conform to company-wide practices and policies.

69. Based on the pattern and practice of fraudulent conduct identified in this complaint, combined with the encouragement and toleration of this conduct by Amgen management, Plaintiff is informed and believes that Amgen has used illegal financial inducements in the manner described above to induce providers to prescribe all of Amgen's drugs.

B. Amgen's Illegal Off-Label Promotion Practices

70. Another facet of Amgen's aggressive marketing strategy involves the off-label promotion of drugs. Amgen's off-label marketing of the drug Sensipar is a representative example of this conduct. The FDA has approved Sensipar for only two indications: (1) the treatment of secondary hyperparathyroidism (secondary HPT) in chronic kidney disease patients on dialysis; and (2) the treatment of hypercalcemia in patients with parathyroid carcinoma. All other uses of Sensipar are unapproved and therefore "off-label."

71. Notwithstanding the legal prohibition against off-label promotion, Amgen is promoting Sensipar for an off-label use, namely, the treatment of renal bone disease.

72. Renal bone disease is a distinct pathology from secondary HPT, Sensipar's on-label indication. Secondary HPT is a condition of the parathyroid glands, and is characterized by elevations in PTH, calcium and phosphorus levels. Sensipar's on-label indication is to reduce excessively high levels of parathyroid hormone and to reduce excessively high levels of serum calcium. If left untreated, patients with secondary HPT may develop into the consequential pathological complication of one form of renal bone disease (high bone turnover disease). Patients with excessively high levels of parathyroid hormone do not necessarily develop the consequential pathology of high bone turnover disease. High bone turnover disease is a condition of the bone,

characterized by over activity of the bone cells responsible for bone turnover, which can lead to excessive release of calcium and phosphate from the bone. The presence of high bone turnover disease is determined by bone biopsy.

73. Because Secondary HPT is a pathological condition of the parathyroid glands, and renal bone disease is a separate pathological condition of the bones, a drug that is approved for treatment of secondary HPT may not be promoted for treatment of renal bone disease unless it receives explicit approval for that indication from the FDA. In order for Amgen to gain approval from the FDA to add claims for the treatment of renal bone disease to the Sensipar label, Amgen would have to undertake the considerable effort and expense of carrying out additional clinical trials. Even then, there is no assurance that the outcome of the trials would justify FDA approval of Sensipar for the treatment of renal bone disease.

74. Clinical trials to prove the effectiveness of Sensipar for the treatment of renal bone disease would have to include the "gold standard" for assessing bone status, which is the bone biopsy. Such clinical trials would have to include two bone biopsies per clinical trial subject - one bone biopsy before treatment with Sensipar, and one bone biopsy after treatment with Sensipar. Moreover, there would likely have to be an interval of approximately one year between the pre and post treatment bone biopsies. It is difficult to find large numbers of patients willing to participate in a two bone biopsy clinical trial. Both the design and the results of such a clinical trial would have to be approved by the FDA before it would allow Amgen to add claims for the treatment of renal bone disease to the Sensipar label. With all of the challenges involved in performing such a bone biopsy clinical trial, the approval process could take several years.

75. As of the date Plaintiff commenced this action, Amgen has performed only very small (less than 100 patients) bone biopsy clinical trials for Sensipar, which were not sufficient for

the FDA to approve Sensipar for the treatment of renal bone disease. Instead, Amgen has pursued the easier and more profitable course of circumventing FDA law, and simply promoting the sale of Sensipar with off-label claims for the treatment of renal bone disease. In doing so, not only has Amgen shown a reckless disregard for FDA law, but also a reckless disregard for the health and safety of one of the most vulnerable populations of society, ESRD patients.

76. Amgen's conduct is made all the more egregious by the fact that Amgen's own bone biopsy based clinical trials have shown that Sensipar is *ineffective* in treating renal bone disease. For example, at the 2004 meeting of the European Renal Association/European Dialysis and Transplantation Association (ERA/EDTA) in Lisbon, Portugal, Dr. Hartmut Malluche (an Amgen paid clinical consultant and world expert in bone biopsy evaluations) presented findings from an Amgen bone biopsy clinical study that demonstrated that Sensipar performed no better than a placebo in treating high turnover renal bone disease. Dr. Malluche's presentation was based on bone biopsies from Amgen's own clinical trials. Dr. Malluche's analysis compared 32 patients treated with Sensipar and 16 patients treated with a placebo, using two bone biopsies (pretreatment and after 48 weeks of treatment) to measure bone turnover. Dr. Malluche's study revealed the following findings:

a. Nine patients treated with Sensipar had a lowering of bone turnover (i.e., Sensipar was 28% effective for treating renal bone disease), and six patients treated with a placebo had a lowering of bone turnover (i.e., the placebo was 38% effective in treating renal bone disease). Thus, the patients treated with the placebo had a proportionately larger success rate in effectiveness in lowering bone turnover;

b. Four Sensipar treated patients showed no change in bone turnover, and two placebo treated patients showed no change in bone turnover (i.e, equal proportion of both groups had that same outcome); and

c. Five Sensipar treated patients showed a rise in bone turnover (opposite of intended outcome), as did four placebo patients.

77. In summary, Dr. Malluche's study, which used the gold standard of bone biopsies to analyze bone turnover, revealed that Sensipar was ineffective in treating renal bone disease (or lowering bone turnover).

78. Notwithstanding that Sensipar is not approved for treatment of renal bone disease, and has been shown to be ineffective for treatment of renal bone disease, Amgen is promoting Sensipar for that off-label indication. Amgen has promoted Sensipar off label for treatment of renal bone disease both in written materials as well as in oral presentations to providers.

79. One example of Amgen's off-label promotion in written materials is a Sensipar brochure entitled, "For Dialysis Patients . . . The Condition You May Know The Least About Can Have A Big Impact On Your Health." Plaintiff obtained this brochure at a physician's office on May 21, 2004. On the front page of this brochure is a picture of an elderly gentleman with a large bone superimposed on his arm. Inside the brochure, there is a description of the symptoms of secondary HPT, i.e., the condition for which Sensipar is approved. After describing the symptoms of secondary HPT, the brochure then states, at page 3, "This condition is called secondary hyperparathyroidism (high-per-pair-uh-THIGH-royd-izm). ***Some people call this bone disease.***" (Emphasis added). This is a blatant example of Amgen representing in promotional material that Sensipar is approved for treating bone disease, when it is not in fact approved for that indication and has not been shown effective for treatment of that condition. In addition to this blatant

example, several other statements in the brochure contribute to the misleading impression that Sensipar is approved for treating bone disease in renal dialysis patients.

80. Plaintiff is informed and believes that Amgen representatives have also promoted Sensipar for treatment of renal bone disease in oral presentations to physicians and clinics. For example, Plaintiff is informed and believe that Amgen sales representatives, including Kathy Smith of Buffalo, New York, and Amgen scientific consultants, including Drs. William Goodman and Geoffrey Block, have promoted Sensipar for the treatment of renal bone disease on behalf of, and with the knowledge of, Amgen.

81. Plaintiff is informed and believes that, as a result of these off-label promotional practices, Amgen has caused physicians and clinics to prescribe Sensipar for off-label treatment of renal bone disease. As a further result of Amgen's unlawful practices, Medicaid and other federal and state health insurance programs have been induced to pay reimbursement claims for these prescriptions - claims that they would not have paid but for the practices complained of herein.

C. Illegal "Marketing The Spread" Practices

82. During the course of his many years working in the medical field, Plaintiff has developed a large number of contacts and has had thousands of hours of conversation about practices in the industry. During the course of these discussions, Plaintiff has learned that "marketing the spread," discussed in the Applicable Law section above, is a widespread practice. Following are instances of marketing the spread and other illegal marketing practices that Plaintiff learned of through discussions with first-hand witnesses to the practices described.

1. Amgen and INN Illegally "Market the Spread" of Aranesp

83. INN (International Nephrology Network) is a group purchasing organization (GPO), which is owned by AmerisourceBergen. INN offers a free membership in the GPO to

nephrologists, which gives the nephrologists access to the GPO's volume discounts on the purchase of pharmaceuticals.

84. INN has business partnerships with various pharmaceutical manufacturers, including Amgen. Among other services it provides, INN assists Amgen in promoting Amgen's pharmaceutical drug Aranesp.

85. Aranesp was approved by the FDA in September 2001 for use in treating anemia associated with chronic kidney failure. Because Aranesp is an injectable drug, it is eligible for Medicare reimbursement at 95 percent of its published AWP. Aranesp is also reimbursed by Medicaid and other federal health programs.

86. Aranesp is a second-generation version of Amgen's Epogen. As noted above, Amgen shares U.S. marketing rights to Epogen with Johnson & Johnson. Johnson & Johnson sells Epogen under the brand name Procrit. Amgen owns the marketing rights to Epogen in the dialysis market, and Johnson & Johnson owns marketing rights to Epogen for non-dialysis use. Plaintiff is informed and believes that Johnson & Johnson does not have marketing rights to Aranesp.

87. Because Aranesp is not subject to this marketing agreement, Amgen has been aggressively promoting Aranesp in the non-dialysis market in an attempt to take market share away from Johnson and Johnson's Procrit. Among other aggressive marketing tactics, Amgen and INN are "marketing the spread" to nephrologists who treat non-dialysis patients in order to induce them to purchase Aranesp for their patients.

88. Amgen and INN market the spread of Aranesp in the following manner. First, Amgen creates a spread by substantially discounting the price of Aranesp to providers and/or by inflating the self-reported AWP for the drug. This spread represents the provider's profit margin,

equal to the difference between the amount a provider pays for Aranesp and the amount the provider receives from Medicare after reselling it to a patient.

89. Once the spread is created, Amgen targets high volume Procrit-prescribing nephrologists that Amgen wants to convert to Aranesp. Amgen identifies these nephrologists from lists purchased from IMS Health ("IMS"), a leading supplier of business intelligence for the pharmaceutical industry. Among other information, IMS sells lists that identify nephrologists by name, and the quantity of Procrit prescribed by each nephrologist.

90. Amgen then provides these lists to INN, together with a print out showing how much money the nephrologist can make from the spread. The print out shows that a nephrologist who prescribes a typical dose of 60 micrograms of Aranesp two times per month for a Medicare pre-dialysis patient will realize a profit of $200 per patient per month, or $2400 per year. Thus, if the nephrologist has 200 Medicare pre-dialysis patients, the nephrologist can make $480,000 per year from the spread. Plaintiff is informed and believes that the INN representatives communicate this information to the nephrologists to induce their purchase of Aranesp.

91. Plaintiff is informed and believes that this "marketing the spread" campaign has induced numerous providers to purchase Aranesp. Marketing the spread of Aranesp in this manner violates the anti-kickback statute, and all claims for federal or state reimbursement of Aranesp induced by this practice violate the federal and state false claims acts. As a result of this practice, the federal and state governments have been damaged in a substantial amount.

92. Plaintiff is informed and believes that the above example of Amgen and INN marketing the spread to sell Aranesp is not unique, and that Amgen, alone or in conjunction with INN and others, has marketed the spread of other Amgen drugs. In Plaintiff's experience, Amgen's sales and marketing practices are directed and coordinated from the company's headquarters. In

Plaintiff's experience, Amgen dictates consistent practices company-wide, and Amgen's sales and marketing personnel throughout the country follow similar practices. Amgen headquarters would not have permitted the practices described above if those practices did not conform to company-wide practices and policies.

93. Based on the pattern and practice of fraudulent conduct identified in this complaint, combined with the encouragement and toleration of this conduct by Amgen management, Plaintiff is informed and believes that Amgen has used marketing the spread to induce providers to prescribe other Amgen drugs.

E. Other Fraudulent Practices

1. INN and Watson Illegally Market Ferrlecit

a. Marketing the Spread of Ferrlecit

94. In addition to its partnership with Amgen, INN also has a business partnership with Watson Pharmaceuticals, Inc. ("Watson"). Watson manufactures the drug Ferrlecit, which is approved for treatment of iron deficiency anemia in patients undergoing chronic hemodialysis. Because Ferrlecit is a Medicare-covered drug, it is eligible for Medicare reimbursement at 95 percent of its published AWP. The patient is responsible for a 20 percent co-pay, with Medicare picking up the balance. Ferrlecit is also reimbursed by Medicaid and other government health programs.

95. Plaintiff is informed and believes that INN and Watson market the spread of Ferrlecit in a manner similar to the way in which INN and Amgen market the spread of Aranesp, described in paragraphs 85 to 89 above. Watson first creates a spread by substantially discounting the price of Ferrlecit to the provider and/or by inflating the self-reported AWP for the drug. This spread represents the provider's profit margin, equal to the difference between the amount a

provider pays for Ferrlecit and the amount the provider receives from Medicare after reselling it to a patient.

96. Once the spread is created, INN then "markets" this spread to nephrologists to induce them to purchase Ferrlecit for their patients. INN representatives explain to the nephrologists that for every Medicare patient placed on a typical dose of Ferrlecit of 2 grams per year, the nephrologists can profit $1200 per gram or $2400 per year for each patient. If a nephrologist has 200 patients on Ferrlecit, the nephrologist can profit $480,000 per year. Plaintiff is informed and believes that the INN representatives communicate this information to the nephrologists to induce their purchase of Ferrlecit. For INN's services, Watson pays INN 1% of the nephrologists' purchases of Ferrlecit.

97. As part of its "marketing the spread" campaign, INN also engages in the off-label promotion of Ferrlecit. The FDA-approved indication for Ferrlecit is very narrow. Ferrlecit's approved product label states:

> Ferrlecit . . . is indicated for treatment of iron deficiency anemia in adult patients and in pediatric patients age 6 years and older undergoing chronic hemodialysis who are receiving supplemental epoetin therapy.

98. As this indication makes clear, Ferrlecit is approved for patients undergoing hemodialysis, but it is not approved for *pre*-dialysis patients.

99. Plaintiff is informed and believes that when INN markets the spread of Ferrlecit to physicians, INN also encourages physicians to use Ferrlecit to treat anemia in pre-dialysis patients, who receive treatment in the physicians' office. This constitutes off-label promotion, since Ferrlecit is not approved for treatment of these patients.

100. Plaintiff was informed of the above practices by a former sales representative of INN who engaged in these practices.

101. Promoting Ferrlecit in the manner described above violates federal and state anti-kickback statutes and food and drug laws. Plaintiff is informed and believes that through these unlawful practices, Watson and INN have knowingly induced numerous providers to purchase and prescribe Ferrlecit and have induced federal and state health insurance programs to pay reimbursement claims for Ferrlecit prescriptions that would not have been paid but for the practices complained of herein.

b. Promoting Medically Unnecessary One-Hour Infusion Therapy To Maximize The Providers' Profits

102. In addition to the practices described above, INN engages in another illegal marketing practice with regard to Ferrlecit. Specifically, INN promotes the reimbursement advantages (and therefore greater profitability to the provider) of administering Ferrlecit by one-hour intravenous infusion rather than by a faster intravenous push injection (typically over 10 minutes). INN engages in this promotional practice *even in circumstances where one hour infusion therapy is not medically necessary*. This promotional practice induces providers to bill government health care programs for medically unnecessary one hour infusion services. This practice also jeopardizes patient safety due to the greater health risks involved in the more lengthy infusion process compared to the shorter intravenous push time.

103. The most basic requirement for reimbursement eligibility under Medicare, Medicaid and other government health care programs is that the services provided must be medically necessary. See, e.g., 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396, et seq.; 42 C.F.R. § 410.50. Providers are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. See id.

104. When Ferrlecit is administered to an eligible patient, Medicare (and other government health care programs) will pay the provider a reimbursement payment for the drug and a separate reimbursement payment for the administration of the drug. The FDA has approved the following methods of administration for Ferrlecit:

> The recommended dosage of Ferrlecit for the repletion treatment of iron deficiency in hemodialysis patients is 10 mL of Ferrlecit (125 mg of elemental iron). Ferrlecit may be diluted in 100 mL of 0.9% sodium chloride administered by intravenous infusion over 1 hour. Ferrlecit may also be administered undiluted as a slow IV injection (at a rate of up to 12.5 mg/min).

105. The Medicare reimbursement payment for administration of Ferrlecit through one-hour infusion is considerably higher than the reimbursement payment for administration through the 10-minute intravenous ("IV") injection. Medicare, however, will only pay for the more expensive one-hour infusion if that method of administration is medically necessary. See 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396, et seq.; 42 C.F.R. § 410.50.

106. Plaintiff is informed and believes that INN representatives have routinely marketed Ferrlecit to providers by emphasizing the greater profits – sometimes amounting to several hundred thousand dollars per year – that can be realized by administering diluted Ferrlecit through a one hour infusion rather than the 10-minute IV push injection. INN has engaged in this marketing practice without regard to the fact that, for the majority of patients for whom Ferrlecit is indicated, one hour infusion therapy of Ferrlecit is not medically necessary.

107. By promoting the reimbursement advantages of the one hour infusion procedure over IV push injection, INN has induced providers to over utilize the one hour infusion procedure, resulting in over billing of Medicare (and other health care programs) for medically unnecessary one hour infusion services. Not only does this practice defraud the government, but it also places patients at undue risk for complications, including increased risk of infection and other

complications that can occur during the more lengthy one hour infusion process compared to the shorter IV push injection.

2. Sigma Tau Illegally Markets The Spread Of Carnitor

108. Sigma-Tau Pharmaceuticals, Inc (Sigma Tau) manufactures Carnitor Injection ("Carnitor"). Carnitor is an "orphan drug" approved by the FDA for the prevention and treatment of carnitine deficiency in dialysis patients. (Carnitine is a naturally occurring amino acid derivative that the body requires for energy production.) Carnitor is an injectable drug that is eligible for Medicare reimbursement at 95 percent of its published AWP. The patient is responsible for a 20 percent co-pay, with Medicare picking up the balance. Carnitor is also reimbursed by Medicaid and other federal health programs.

109. Plaintiff is informed and believes that Sigma Tau markets the spread of Carnitor in the following manner. Sigma Tau creates a spread by substantially discounting the price of Carnitor to the provider and/or by inflating the AWP for the drug. This creates a profit margin for the provider, equal to the difference between the amount a provider pays for Carnitor and the amount the provider receives from Medicare after reselling it to a patient.

110. Sales representatives of Sigma Tau then "market" this spread to providers in a variety of ways to induce them to purchase Carnitor. For example, plaintiff is informed and believes that Sigma Tau sales representatives are allowed to offer independent dialysis clinics a "standard contract" in which the clinics can make approximately $6 per dose profit due to the spread.

111. Plaintiff is further informed and believes that Sigma Tau sales representatives entice other providers to purchase Carnitor by promising even greater profits due to the spread. Sigma Tau sales representative explain to certain providers that the AWP for Carnitor is approximately

$30 per unit and that Sigma Tau will sell it to the provider for $15 per unit, resulting in a $15 profit to the provider.

112. Plaintiff is informed and believes that this "marketing the spread" campaign has induced numerous providers to purchase Carnitor.

113. Sigma Tau's practice of marketing the spread to induce purchases of Carnitor violates the anti-kickback statute, and all claims for federal or state reimbursement of Carnitor induced by this practice violate the federal and state false claims acts. As a result of this practice, the federal and state governments have been damaged in a substantial amount.

Count I
False Claims Act,
31 U.S.C. §§3729(a)(1)-(3), (7)

114. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

115. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

116. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

117. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to induce the United States Government to approve and pay such false or fraudulent claims.

118. By virtue of the acts described above, defendants conspired with each other and with others to defraud the United States by inducing the United States Government to pay or approve false or fraudulent claims.

119. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States Government. As a result, monies were lost to the United States through the non-payment or non-transmittal of money or property owed to the United States by the defendants

120. Each sale of a drug and each prescription for a drug that was a result of defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such drugs submitted to a federal health insurance program represents a false or fraudulent claim for payment.

121. Plaintiff cannot at this time identify all of the false claims for payment that were caused by defendants' conduct. The false or fraudulent claims were presented by thousands of separate entities across the United States. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

122. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

123. By reason of defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid numerous claims for drugs that were purchased or prescribed as a result of defendants' illegal inducements and/or business practices.

Count II
California False Claims Act
Cal Govt Code §12651(a)(1)-(3), (7)

124. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

125. This is a claim for treble damages and penalties under the California False Claims Act.

126. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

127. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

128. By virtue of the acts described above, defendants conspired with each other and with others to defraud the California by inducing the California State Government to pay or approve false or fraudulent claims.

129. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the California State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

130. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and

continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

131. By reason of the defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

132. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count III
Delaware False Claims And Reporting Act
6 Del C. §1201(a)(1)-(3), (7)

133. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

134. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

135. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

136. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

137. By virtue of the acts described above, defendants conspired with each other and with others to defraud Delaware by inducing the Delaware State Government to pay or approve false or fraudulent claims.

138. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or

transmit money or property to the Delaware State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

139. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

140. By reason of the defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

141. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count IV
Florida False Claims Act
Fla. Stat. Ann. §68.082(2)

142. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

143. This is a claim for treble damages and penalties under the Florida False Claims Act.

144. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

145. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

146. By virtue of the acts described above, defendants conspired with each other and with others to defraud Florida by inducing the Florida State Government to pay or approve false or fraudulent claims.

147. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Florida State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

148. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants'illegal inducements and/or business practices.

149. By reason of the defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

150. The State of Florida is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count V
Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)

151. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

152. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

153. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

154. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

155. By virtue of the acts described above, defendants conspired with each other and with others to defraud Hawaii by inducing the Hawaii State Government to pay or approve false or fraudulent claims.

156. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Hawaii State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

157. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

158. By reason of the defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

159. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count VI

Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. §175/3(a)(1)-(3), (7)

160. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

161. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

162. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

163. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

164. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

165. By virtue of the acts described above, defendants conspired with each other and with others to defraud Illinois by inducing the Illinois State Government to pay or approve false or fraudulent claims.

166. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Illinois State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

167. By reason of the defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

168. The State of Illinois is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count VII
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(1)-(3), (7)

169. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

170. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

171. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

172. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

173. By virtue of the acts described above, defendants conspired with each other and with others to defraud Massachusetts by inducing the Massachusetts State Government to pay or approve false or fraudulent claims.

174. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Massachusetts State Government. As a result, monies were lost

to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

175. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

176. By reason of the defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

177. The State of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count VIII
Nevada False Claims Act
Nev. Rev. Stat. Ann. §357.040(1)(a)-(c), (g)

178. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

179. This is a claim for treble damages and penalties under the Nevada False Claims Act.

180. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

181. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

182. By virtue of the acts described above, defendants conspired with each other and with others to defraud Nevada by inducing the Nevada State Government to pay or approve false or fraudulent claims.

183. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Nevada State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

184. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

185. By reason of the defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

186. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count IX
New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-14-1 et seq. and New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §44-9-1 et seq

187. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

188. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act.

189. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

190. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

191. By virtue of the acts described above, defendants conspired with each other and with others to defraud New Mexico by inducing the New Mexico State Government to pay or approve false or fraudulent claims.

192. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the New Mexico State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

193. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

194. By reason of the defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

195. The State of New Mexico is entitled to civil penalties for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count X
Tennessee Medicaid False Claims Act
Tenn. Code Ann. §71-5-182(a)(1)

196. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

197. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Law.

198. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

199. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

200. By virtue of the acts described above, defendants conspired with each other and with others to defraud Tennessee by inducing the Tennessee State Government to pay or approve false or fraudulent claims.

201. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Tennessee State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

202. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and

continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

203. By reason of the defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

204. The State of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XI
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §36.002

205. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

206. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

207. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

208. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

209. By virtue of the acts described above, defendants conspired with each other and with others to defraud Texas by inducing the Texas State Government to pay or approve false or fraudulent claims.

210. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or

transmit money or property to the Texas State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

211. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

212. By reason of the defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

213. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XII
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(1)-(3), (7)

214. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

215. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

216. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

217. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

218. By virtue of the acts described above, defendants conspired with each other and with others to defraud Virginia by inducing the Virginia State Government to pay or approve false or fraudulent claims.

219. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Virginia State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

220. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

221. By reason of the defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

222. The State of Virginia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XIII
District of Columbia False Claims Act
D.C. Code Ann. § 2-308.14 (a)(1)-(3), (7)

223. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

224. This is a claim for treble damages and penalties under the District of Columbia False Claims Act.

225. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

226. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

227. By virtue of the acts described above, defendants conspired with each other and with others to defraud the District of Columbia by inducing the District of Columbia Government to pay or approve false or fraudulent claims.

228. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District of Columbia Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

229. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

230. By reason of the defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

231. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XIV
Georgia False Medicaid Claims Act
O.C.G.A. §§ 49-4-168 et seq.

232. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

233. This is a claim for treble damages and penalties under the Georgia False Medicaid Claims Act.

234. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

235. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

236. By virtue of the acts described above, defendants conspired with each other and with others to defraud Georgia by inducing the Georgia State Government to pay or approve false or fraudulent claims.

237. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Georgia State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

238. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

239. By reason of the defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

240. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XV
Indiana False Claims and Whistleblower Protection Act
I.C. 5-11-5.5

241. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

242. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

243. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

244. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

245. By virtue of the acts described above, defendants conspired with each other and with others to defraud Indiana by inducing the Indiana State Government to pay or approve false or fraudulent claims.

246. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Indiana State Government. As a result, monies were lost to the

State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

247. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

248. By reason of the defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

249. The State of Indiana is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XVI
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §437 et. seq

250. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

251. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

252. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

253. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

254. By virtue of the acts described above, defendants conspired with each other and with others to defraud Louisiana by inducing the Louisiana State Government to pay or approve false or fraudulent claims.

255. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Louisiana State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

256. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

257. By reason of the defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

258. The State of Louisiana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XVII
Michigan Medicaid False Claims Act
MCL 400.601-400.613

259. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

260. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

261. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

262. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

263. By virtue of the acts described above, defendants conspired with each other and with others to defraud Michigan by inducing the Michigan State Government to pay or approve false or fraudulent claims.

264. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Michigan State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

265. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

266. By reason of the defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

267. The State of Michigan is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XVIII

New York False Claims Act
N.Y. State Fin. §§ 187 et. seq.

268. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

269. This is a claim for treble damages and penalties under the New York State False Claims Act.

270. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

271. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

272. By virtue of the acts described above, defendants conspired with each other and with others to defraud New York by inducing the New York State Government to pay or approve false or fraudulent claims.

273. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the New York State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

274. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and

continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

275. By reason of the defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

276. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XIX
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §167:61-b(I)(a), (b), and (e)

277. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

278. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

279. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

280. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

281. By virtue of the acts described above, defendants conspired with each other and with others to defraud New Hampshire by inducing the New Hampshire State Government to pay or approve false or fraudulent claims.

282. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the New Hampshire State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

283. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

284. .By reason of the defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

285. The State of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XX
Oklahoma Medicaid False Claims Act
63 Okl. St. § 5053

286. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

287. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

288. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

289. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

290. By virtue of the acts described above, defendants conspired with each other and with others to defraud Oklahoma by inducing the Oklahoma State Government to pay or approve false or fraudulent claims.

291. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Oklahoma State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

292. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

293. By reason of the defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

294. The State of Oklahoma is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XXI
Connecticut False Claims Act
Conn. Publ Law 09-05

295. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

296. This is a claim for treble damages and penalties under the Connecticut False Claims Act.

297. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval.

298. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut State Government to approve and pay such false and fraudulent claims.

299. By virtue of the acts described above, defendants conspired with each other and with others to defraud Connecticut by inducing the Connecticut State Government to pay or approve false or fraudulent claims.

300. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Connecticut State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

301. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

302. By reason of the defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

303. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XXII
New Jersey False Claims Act
N.J. Stat. § 2A: 32C-1 et seq.

304. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

305. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

306. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

307. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

308. By virtue of the acts described above, defendants conspired with each other and with others to defraud New Jersey by inducing the New Jersey State Government to pay or approve false or fraudulent claims.

309. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the New Jersey State Government. As a result, monies were lost to

the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

310. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

311. By reason of the defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

312. The State of New Jersey is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XXIII
Rhode Island False Claims Act
R.I. Gen. Laws § 9-1.1-1 *et seq.*

313. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

314. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

315. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

316. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

317. By virtue of the acts described above, defendants conspired with each other and with others to defraud Rhode Island by inducing the Rhode Island State Government to pay or approve false or fraudulent claims.

318. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Rhode Island State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

319. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

320. By reason of the defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

321. The State of Rhode Island is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count XXIV
Wisconsin False Claims For Medical Assistance Act
Wis. Stat §20.931 et seq

322. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 113 of this Complaint.

323. This is a claim for treble damages and penalties under the Wisconsin False Claims For Medical Assistance Act.

324. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

325. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

326. By virtue of the acts described above, defendants conspired with each other and with others to defraud Wisconsin by inducing the Wisconsin State Government to pay or approve false or fraudulent claims.

327. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Wisconsin State Government. As a result, monies were lost to the State through the non-payment or non-transmittal of money or property owed to the State by the defendants.

328. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

329. By reason of the defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

330. The State of Wisconsin is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Prayer

1. WHEREFORE, Plaintiff prays for judgment that defendants cease and desist from violating 31 U.S.C. §3729 et seq., and the equivalent provisions of the state statutes set forth above;

2. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of California has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §12651(a);

4. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

5. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of Fla. Stat. Ann. §68.082;

6. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-21(a);

7. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

8. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

9. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

10. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of defendants' actions, plus civil penalties for each violation of N.M. Stat. Ann. §27-14-1 et seq.and N.M. Stat. Ann. §44-9-1 et seq;

11. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendants' actions, plus a civil penalty for each violation of Tenn. Code Ann. §71-5-182(a);

12. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

13. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. §8.01-216.3(a);

14. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14(a);

15. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of O.C.G.A §§ 49-4-168 et seq;

16. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of defendants' actions, plus civil penalties for each violation of I.C. §5-11-5.5;

17. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §437 et. seq.;

18. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of MCL 400.601 et seq.;

19. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of defendants' actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b(I);

20. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New York has sustained because of defendants' actions, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. §§ 187 et seq.;

21. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 63 Okl. St. § 5053 et seq.

22. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Conn. Publ. Law 09-05.;

23. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of defendants' actions, plus civil penalties for each violation of N.J. Stat. §2A:32C-1 et seq.;

24. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of defendants' actions, plus civil penalties for each violation of R.I. Gen. Laws §9-1.1-1 et seq.;

25. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the Wisconsin has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of the Wis. Stat. §20.931 et seq.;

26. that Plaintiff be awarded the maximum amount allowed pursuant to §3730(d) of the federal False Claims Act, and the equivalent provisions of the state statutes set forth above;

27. that Plaintiff be awarded all costs of this action, including attorneys' fees and expenses; and

28. that Plaintiff recover such other relief as the Court deems just and proper, or that is necessary to make Plaintiff whole.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury.

Dated: October 30, 2009

PHILLIPS & COHEN LLP

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